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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,196	05/24/2001	Kok-Hwee Ng	F4-5728 (1417P P 591)	2014

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EXAMINER	
SHAPIRO, JEFFERY A	

ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,196	NG ET AL.	
	Examiner	Art Unit	
	Jeffrey A. Shapiro	3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-64 and 66-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-64 and 66-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/06 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 58-64 and 66-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher-Haynes et al (US 2001/0034614 A1) (herein referred to as Fletcher.

4. Fletcher discloses a system for monitoring and tracking an entire blood component collection procedure in a blood component facility, performed upon a donor by an operator, as follows.

As described in Claims 58 and 82;

a. a blood component collection instrument (10'),(see figure 7a) for collecting a blood component from a donor;

b. the donor having a donor identifier (see paragraph 159) and the blood component collection instrument having a blood collection instrument identifier (ibid);

c. a central input station (140 and 144) being operably connected to the blood component collection instrument (see figure 1a-1d), the central input station comprising a program having a plurality of code segments, at least one code segment monitoring operation of a blood component collection instrument *during and throughout operation of the blood component collection instrument;*

(See paragraphs 20, 24, 59, 74, 83, 154-159.)

d. a memory (142) operably connected to the system server, the memory for storing information received by the central input station (see paragraph 59 and 65);

e. an interface (199)-see paragraph 57) operably connected to the system server, the interface having a display for monitoring the at least one portion of the blood component collection procedure;

f. a blood component inventory database (see para's 11, 194, 195 and 314);

At the time of the invention, it would have been obvious to one of ordinary skill to inventory blood component kits in Fletcher's system since they are an important part of the blood collection process. Fletcher's inventory control structure can be used to

inventory blood collection supplies such as blood collection kits since Fletcher's inventory includes blood collection kits and would therefore necessarily be inventoried. Fletcher at para 11 mentions that blood components are inventoried. Note also that Fletcher's system handles inventory of blood products, and is a system connected to the internet, as described in para's (194, 195). Suggestion/motivation is found in Fletcher's para 314, which mentions that the system can be used in "other applications relating to enhancing blood component system management" (314, lines 1-4), of which inventory of collection kits is one such application. Fletcher, at para 22, describes having "bar code capability" for entry of various collection item data such as, for example, collection tubes. Such tubes can be construed as a "blood component collection kit". In the alternative, even if these tubes are only construed as part of a kit or just a component other than the kit, it would have been obvious for one ordinarily skilled to have included blood collection kits, used or unused, in Fletcher's inventory database because such blood collection kits are integral to the blood component collection process.

Additionally, further regarding a "blood component collection kit having a blood component collection kit identifier, the blood component collection kit for collecting the blood component from the donor" as recited in Claims 58 and 82, note that Fletcher, at paragraph 315 describes the use of an appropriate container to store blood. It is considered to be obvious that Fletcher's apparatus is designed to be used with a standard blood collection kit, said kit having an identification means such as a label with barcode, so as to allow identification and connection with a particular patient/donor and

collection procedure since the blood must be tracked from the donor to the patient to secure against problems with the blood based on the donor's health condition, or allow for subsequent investigation of problems of the blood drawing procedure due to equipment failure. See also paragraph 195, which describes use of a barcode for identification and paragraph 59, which indicates that a barcode reader is connected to a central system (140).

Fletcher further discloses the following.

As described in Claims 59 and 82;

g. a report comprising information from the memory, the information in the memory being selected from the group consisting of data blood component collection instrument data, operator data and donor data (see para's 12, 18, 19, 26, 75, 77 and 166);

As described in Claims 60 and 82;

h. the interface comprises a reader (see again para 195, which describes use of a barcode for identification and para 59, which indicates that a barcode reader is connected to central system (140).

As described in Claim 61;

i. a blood component collection process number is associated with the blood component collection procedure, the donor, the blood collection kit and the blood collection instrument, wherein the interface transmits the

donor identifier, the collection kit identifier and the blood component collection instrument identifier to the system server;

(See also para 159 which describes the plethora of identification information used by Fletcher's system and para 195, which describes use of a barcode for identification and paragraph 59, which indicates that a barcode reader is connected to central system (140).)

As described in Claim 62;

j. the interface is remotely located from the blood component collection instrument (note that the central system (140) is located at a point away from the blood collection instrument as shown in figures 1a-1d);

As described in Claim 63;

k. a blood component collection process number is associated with the blood component, and wherein the blood component collection instrument identifier, the blood donor identifier and the blood component collection process number are associated with the blood collection kit;

(See also para 159 which describes the plethora of identification information used by Fletcher's system and para 195, which describes use of a barcode for identification and paragraph 59, which indicates that a barcode reader is connected to central system (140).)

As described in Claim 64;

l. a label is created in response to a change of status of the blood component collection kit;

(See para 183, which indicates that the system reminds the operator to place a label the platelet product, i.e., the container, which is construed as the collection kit.)

As described in Claim 66;

m. the program automatically updates the blood collection kit inventory database in response to the blood collection kit identifier being input into the interface;

(See previous discussion of Claim 65.)

As described in Claim 67;

n. a remote server operably connected to the system server via a communication network, the remote server monitoring and tracking a remote blood collection facility;

(See para's 194, 195)

As described in Claim 68;

o. the interface comprises a screen menu for providing information about the blood collection kit;

(Again, see para 159, which lists numerous information about the blood collection procedure, and para 183, which indicates that the system

reminds the operator to place a label on the platelet product, i.e., the container, which is construed as the collection kit.)

As described in Claims 69 and 82;

p. the interface comprises;

i. a reader for entering information;

ii. a transmitter for transmitting information to the server;

(See para 159 which describes the plethora of identification information used by Fletcher's system and para 195, which describes use of a barcode for identification and paragraph 59, which indicates that a barcode reader is connected to central system (140).

As described in Claims 70 and 82;

q. a receiver for receiving information from the server;

(Note that several parts of Fletcher's system can be construed as receivers of information from the server, as the machine controllers of the blood collection machine are controlled by information from the server. See again para's 20, 24, 59, 74, 83, 154-159.)

r. a web browser cooperating with the server, the web browser for displaying information saved in the memory;

(See again, para's 194, 195.)

As described in Claim 70;

s. the interface utilizes radio frequency to transmit to the system server;

At the time of the invention, it would have been obvious that radio frequency would have been used to transmit to the system server of Fletcher, and that even if another frequency is used, that it is considered to be an obvious variation of Applicant's frequency and that Fletcher's system will work substantially as Applicant's system, regardless of the frequency range used for intersystem communications. Further, Applicant's provide no particular reason for using one frequency over another.

As described in Claims 71 and 72;

t. the reader comprises a touch pad for entering information into the program;

u. the reader comprises a touch pad for entering information into the program;

(See para 287, lines 8 and 9, which mentions use of a touch screen.)

As described in Claim 73;

v. the interface comprises a stylus for cooperating with the touch pad wherein written text can be entered;

(Note that regardless of whether or not a stylus is used with Fletcher's touch screen, Fletcher's system will work substantially as Applicant's.)

As described in Claim 74;

w. the reader comprises a keypad (149a)for entering information into the program (see para 59);

As described in Claim 75;

x. the reader comprises an optical scanner for entering information into the program (note that the previously mentioned bar code reader of is such a scanner);

As described in Claim 76;

y. the reader comprises a magnetic scanner for entering information into the program (note that this is a functional equivalent of a bar code reader);

As described in Claim 77;

Z. the interface comprises a menu for monitoring the at least one portion of the blood component collection procedure (see figures 6a and 6m);

As described in Claim 78, 89 and 90;

aa. the interface comprises a menu for tracking the at least one portion of the blood component collection procedure;

(See figures 6a and 6m, for example.)

As described in Claim 79;

ab. a communication conduit operably connecting the blood component collection instrument to the system server (see figure 1c, noting elements 1215, 1210, 1212, 140a, 1222, 146b and 1225); and

ac. a web interface being operably connected to the system server, the web interface providing access to the system server for monitoring the at least one portion of the blood component collection procedure (see again, para's 194, 195);

As described in Claim 80;

ad. the communication conduit utilizes Ethernet (see para 30);

As described in Claim 81;

ae. wherein the communication conduit utilizes TCP/IP (see again para's 194, 195);

5. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher in view of Quattrocchi (US 5,978,466). Fletcher discloses the blood collection system described above. Fletcher does not expressly disclose but Quattrocchi discloses the following.

As described in Claim 83;

af. a fifth segment of the computer readable medium for determining eligibility of the donor (note that it is well known that blood screening is

used by the red cross to screen for items such as hepatitis or HIV—see Quattrocchi (US 5,978,466) which describes a method for testing for HIV, as well as another system which tracks a blood component sample, kit and donor/patient);

Fletcher and Quattrocchi are considered to be analogous art because they both concern blood collection and analysis.

At the time of the invention, it would have been obvious to use an HIV screening function in Fletcher's blood collection system, integrating them so as to work in concert with each other.

The suggestion/motivation would have been to screen blood from various donors for HIV or other blood-borne diseases. See Quattrocchi, col. 3, line 66-col. 4, line 6. This screening system would better provide a way to control healthcare costs, among other things as well as to provide more complete data for bio-emergencies such as disease outbreaks which might affect the blood supply as well as blood usage problems which might strain the blood component supply system.

6. Claims 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher in view of Quattrocchi (US 5,978,466) and further in view of Baluyot et al (US 5,132,026).

Fletcher discloses the blood collection system described above. Regarding Claims 84 and 85, Fletcher discloses linking various identification information

concerning the blood collection procedure, as described in para 159. Regarding Claims 87 and 88, Fletcher also discloses report generation, as discussed above.

Fletcher does not expressly disclose but Baluyot discloses the following.

As described in Claims 84, 86;

ag. a sixth segment for generating a bleed number (see Baluyot et al, col. 3, lines 6-40);

Fletcher and Baluyot and Brown are considered to be analogous art because they both concern blood collection and analysis.

At the time of the invention, it would have been obvious to have generated a bleed number for use in Fletcher's system, as is well-known in the art.

Note also that Baluyot et al is teaches the use of barcode identifiers in the form of labels for linking the sample containers, the collection instrument, and the bleed number, again, as described above.

The suggestion/motivation for using Baluyot's teaching regarding barcodes linking containers and bleed numbers is that Langley is a blood component collection system and would require linking containers with blood from specific patients with their bleed numbers, a particular characteristic of the patient's blood donation process. Note also that it would have been expedient to identify and link any number of variables,

including a bleed number, and items required in such a procedure as taking blood, since it is important to manage this important resource to the medical community.

Response to Arguments

7. Applicant's arguments filed 3/17/06 have been fully considered but they are not persuasive. Applicant asserts that Fletcher does not read on Applicant's independent claims because Fletcher does not disclose maintaining inventory of "unused" blood collection kits. However, Fletcher, as described above, does mention blood component collection device (18), for example. Such a device would have been part of a standard blood collection kit, as is well-known in the industry. See again, Baluyot's teaching regarding tracking containers with specific patients. One ordinarily skilled in the art would consider it important to track all items used in a blood collection procedure, and therefore the items making up a "blood collection kit" since any problems with the blood or the patient after the procedure must be investigated, and could involve defects in the blood collection instruments used in the blood collection process.

Again, note Fletcher, at para 22, which describes having "bar code capability" for entry of various collection item data such as, for example, collection tubes. Such tubes can be construed as a "blood component collection kit". In the alternative, even if these tubes are only construed as part of a kit or just a component other than the kit, it would have been obvious for one ordinarily skilled to have included blood collection kits, used or unused, in Fletcher's inventory database because such blood collection kits are integral to the blood component collection process.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (571)272-6943. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene O. Crawford can be reached on (571)272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JAS

July 7, 2006

GENE O. CRAWFORD
SUPERVISORY PATENT EXAMINER